

**JUN - 2 2000 Elox Active Fixation Endocardial Lead  
Special 510(k) Notification****1. 510(K) SUMMARY****Name and Address of Sponsor:**

BIOTRONIK, Inc.  
6024 Jean Road  
Lake Oswego, OR 97035

**Establishment Registration Number:**

1028232

**Device Name:**

Proprietary Name: Elox 45 BP Leads  
Classification: Class III (21 CFR 870.3680(b))  
Classification Name: Cardiovascular Permanent  
Pacemaker Electrode  
Product Code: DTB

**Date Prepared:**

May 3, 2000

**General Description:**

Elox are straight, bipolar endocardial pacing leads that utilize an electrically active extendable/retractable fixation helix. The extendable/retractable fixation helix is comprised of a 70% Pt / 30% Ir alloy with a fractal Iridium coating. The non-insulating distal sleeve, consisting of an inner and outer sleeve, is composed of Polyurethane (Pellethane 2363-75D). The leads contain two conductors composed of quadrifilar MP35N wire in coaxial configurations and are insulated with silicone tubing. A 3.2 mm IS-1 bipolar connector attaches the lead to the pulse generator. The Elox lead is available in lead lengths of 45 cm, 53 cm, and 60 cm.

**Device Modification:**

The proposed Elox 45-BP lead in this Special 510(k) notification is a modified version of BIOTRONIK's currently marketed Elox leads (510(k) #K994240, cleared 04-13-00). The modification to the Elox 45-BP lead is a reduction in the diameter of the inner conductor wire from 0.19 mm to 0.15 mm. The Elox 45-BP leads with an inner conductor wire diameter of 0.15 mm are intended to replace the currently marketed Elox 45-BP leads. In addition, the lead fixation sleeve provided with each Elox lead has been changed from the EFH-25 suture sleeve to the EFH-27.

**Predicate Devices:**

BIOTRONIK proposes the following leads cleared through 510(k) notifications as predicate devices for the Elox 45-BP lead:

- BIOTRONIK's Elox bipolar, active fixation, endocardial leads (#K994240, cleared 04/13/00)

**Indications for Use:**

BIOTRONIK's **ELOX** transvenous, active fixation endocardial leads are indicated for permanent pacing and sensing. Active fixation pacing leads with a bipolar (BP) IS-1 connector configuration are designed for use in conjunction with implantable pulse generators with IS-1 headers. The leads may be used with single or dual chamber pacing systems.

The **ELOX** lead models are intended for placement in either the right atrium or right ventricle.

**Name and Address of Manufacturing Site:**

BIOTRONIK GmbH & Co. (reg. no. 7010992)  
Woermannkehre 1, 12359 Berlin, Germany  
011-49-30-689-05-304

**Contact Person:**

Jon Brumbaugh  
Director, Regulatory Affairs  
Phone (888) 345-0374  
Fax (503) 635-9936



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN - 2 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Jon Brumbaugh  
Director, Regulatory Affairs  
BIOTRONIK, Inc.  
6024 Jean Road  
Lake Oswego, OR 97035

Re: K001413  
Trade Name: ELOX 45-BP Active-Fixation Endocardial Pacing Leads  
Regulatory Class: III (three)  
Product Code: DTB  
Dated: May 3, 2000  
Received: May 4, 2000

Dear Mr. Brumbaugh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

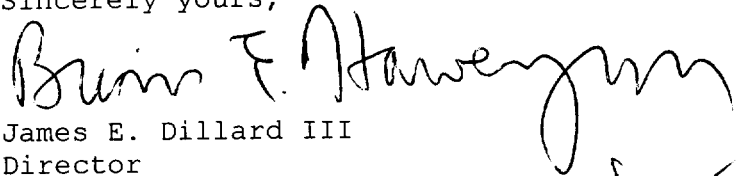
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

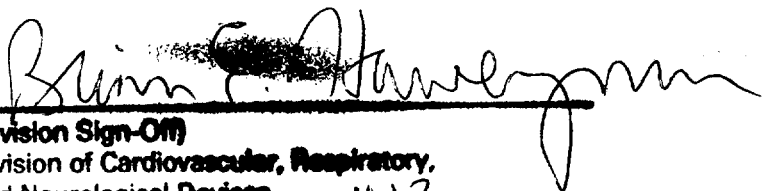


Enclosure

## 2. INDICATIONS FOR USE

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(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number 600413